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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,329	10/28/2003	David Schneider	SDR-10802/01	4848
25006 7590 08/09/2007 GIFFORD, KRASS, SPRINKLE, ANDERSON & CITKOWSKI, P.C PO BOX 7021 TROY, MI 48007-7021			EXAMINER NGUYEN, HUONG Q	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 08/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No. 10/695,329	Applicant(s) SCHNEIDER, DAVID	
	Examiner Helen Nguyen	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This Office Action is responsive to the RCE filed 1/17/2007. Claims 1 and 11 are amended. Claims 1-22 remain pending.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged, namely, priority to provisional application #60421823, filed on 10/28/2002.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1-5 and 9-10** are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Angelo (5910122) in view of Thieme et al (5871905).

5. In regards to **Claim 1**, D'Angelo discloses a kit for the collection and preservation of a saliva sample for subsequent assay of a biologic therein comprising:

a container 10, a saliva collection device 1 and 2, the device including a suction means 17 (Col.4: 3-7) and an exterior surface of "saliva collector" (1) and having a salivation catalyst positioned directly on the exterior surface 1 (Col.5: 3-5), best seen in Figures 1-2.

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6. However, D'Angelo does not disclose a preservation solution retained within said container. Thieme et al teaches it is known to provide a storage vial with a preservation solution inside to maintain the integrity and prevent contamination of the sample during transportation before analysis (Col.11: 39-45). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of D'Angelo to include a preservative solution within the container, as taught by Thieme et al, to maintain the integrity and prevent contamination of the sample during transportation before analysis.

7. In regards to **Claim 2**, D'Angelo discloses the container 10 comprises a resealable tube.

8. In regards to **Claim 3**, D'Angelo discloses the resealable tube comprises a polyethylene transfer vial (Col.5: 43-45).

9. In regards to **Claim 4**, D'Angelo discloses the saliva collection device 1, 2 comprises a transfer pipette 2 having a compression end 17 and an intake end, best seen in Figure 1-2.

10. In regards to **Claim 5**, D'Angelo discloses the salivation catalyst comprises a food flavoring (Col.5: 3-5).

11. In regard to **Claims 9-10**, Thieme et al disclose the preservative solution comprises a fungicide and a bactericide (Col.5: 65-68).

12. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Angelo in view of Thieme et al, as applied to claim 5 above, and further in view of Aronowitz (US Pat No. 20010008614).

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13. D'Angelo as modified by Thieme et al disclose food flavoring salivation catalyst but do not disclose the flavoring being selected from a group consisting of lemon, peppermint, spearmint and orange flavorings. Aronowitz teaches it is well known in the art to provide a flavoring that includes lemon, lime, orange or the like (§0017) to stimulate a person's saliva production. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of D'Angelo as modified by Thieme et al such that the flavoring is selected from a group consisting of lemon, peppermint, spearmint and orange flavorings, as taught by Aronowitz, to effectively stimulate saliva production.

14. **Claims 7 and 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Angelo in view of Thieme et al, further in view of Putcha et al (US Pat No. 6133036).

15. D'Angelo as modified by Thieme et al above discloses the claimed invention except for preservative solution comprising: sodium chloride, NaHPO_4 and NaH_2PO_4 in an aqueous concentration to provide a 50mM phosphate solution and 0.5-2.0 g sodium benzoate. However, the applicant provides two other preservative solutions that can also be used in the same application and device on p.12 of the specification. Therefore the solution is deemed not to be a critical component of the current application and at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a preservative solution of sodium chloride, NaHPO_4 and NaH_2PO_4 in an aqueous concentration to provide a 50mM phosphate solution and .5-2.0 g sodium benzoate. Applicant has not disclosed the specifics of the solution providing an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Putcha et al's

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preservative solution, and applicant's invention, to perform equally well with either the solution taught by Putcha et al or the claimed solution because both solutions would perform the same function of preserving the collected sample equally well. Therefore, it would have been prima facie obvious to further modify D'Angelo as modified by Thieme et al to obtain the invention as specified in claims 7 and 8 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Putcha et al.

16. **Claims 11-18, 21, and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Thieme et al in view of D'Angelo.

17. In regards to **Claim 11**, Thieme et al disclose a method of assaying for a biologic comprising the steps of:

- providing a container (Col.11: 39-45);
- providing a preservative solution within the container (Col.11: 39-45);
- providing a saliva collection device, best seen in Figures 1A and 1B;
- collecting at a first location a saliva sample directly from a mouth of a user using the saliva collection device (Col.11: 22-33);
- depositing the saliva collection device having the saliva sample into the container (Col.11: 34-35);
- and sealing the container having the saliva collection device against spillage and tampering (Col.11: 39-59).

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18. However, Thieme et al do not disclose said saliva collection device includes a suction means an exterior surface and having a salivation catalyst positioned directly on the exterior surface. Thieme et al does disclose that the saliva may be collected using any of a number of known means (Col.7: 42-43). D'Angelo discloses an effective saliva collection device 1, 2 the device including suction means 17 and an exterior surface on "saliva collector" 1 and having a salivation catalyst positioned on the exterior surface (Col.5: 3-5) to collect saliva samples for body fluid constituent analysis, best seen in Figures 1-2. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the saliva collection device of D'Angelo with the method of Thieme et al as an equally as effective saliva collection device to effectively collect saliva samples for body fluid constituent analysis.

19. In regard to **Claims 12-14**, Thieme et al disclose shipping the container having the saliva collection device to a second location and assaying the saliva sample and preservative solution for a biologic at the second location (Col.11: 46-51; Col.12: 4-9).

20. In regards to **Claim 15**, Thieme et al discloses the claimed method except for the container comprising a resealable tube. D'Angelo teaches it is known to provide a resealable tube 10 to allow for reopening and closing of the tube to perform multiple analyses on the sample as well as other functional use. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Thieme et al to include a resealable container, as taught by D'Angelo, to allow for reopening and closing of the tube to perform multiple analyses on the sample and other functional uses.

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21. In regards to **Claim 16**, D'Angelo discloses the resealable tube comprises a polyethylene transfer vial (Col.5: 43-45).

22. In regards to **Claim 17**, D'Angelo discloses the saliva collection device 1, 2 comprises a transfer pipette 2 having a compression end 17 and an intake end, best seen in Figure 1-2.

23. In regards to **Claim 18**, D'Angelo discloses the salivation catalyst comprises a food flavoring (Col.5: 3-5).

24. In regard to **Claims 21-22**, Thieme et al disclose the preservative solution comprises a fungicide and a bactericide (Col.5: 65-68).

25. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Thieme et al in view of D'Angelo, and further in view of Aronowitz.

26. Thieme et al as modified by D'Angelo disclose food flavoring salivation catalyst but do not disclose the flavoring being selected from a group consisting of lemon, peppermint, spearmint and orange flavorings. Aronowitz teaches it is well known in the art to provide a flavoring that includes lemon, lime, orange or the like (§0017) to stimulate a person's saliva production. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Thieme et al as modified by D'Angelo such that the flavoring is selected from a group consisting of lemon, peppermint, spearmint and orange flavorings, as taught by Aronowitz, to effectively stimulate saliva production.

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27. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Thieme et al in view of D'Angelo, further in view of Putcha et al.

28. Thieme et al as modified by D'Angelo above discloses the claimed invention except for preservative solution comprising: sodium chloride, NaHPO_4 and NaH_2PO_4 in an aqueous concentration to provide a 50mM phosphate solution and 0.5-2.0 g sodium benzoate. However, the applicant provides two other preservative solutions that can also be used in the same application and device on p.12 of the specification. Therefore the solution is deemed not to be a critical component of the current application and at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a preservative solution of sodium chloride, NaHPO_4 and NaH_2PO_4 in an aqueous concentration to provide a 50mM phosphate solution and .5-2.0 g sodium benzoate. Applicant has not disclosed the specifics of the solution providing an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Putcha et al's preservative solution, and applicant's invention, to perform equally well with either the solution taught by Putcha et al or the claimed solution because both solutions would perform the same function of preserving the collected sample equally well. Therefore, it would have been prima facie obvious to further modify Thieme et al as modified by D'Angelo to obtain the invention as recite because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Putcha et al.

Response to Arguments

29. Applicant's arguments filed 10/12/2006 have been fully considered but they are not persuasive. Applicant contends that D'Angelo does not disclose a salivation catalyst positioned directly on the exterior surface. However, as already elaborated in the above rejection, D'Angelo discloses a saliva collection device defined by both saliva collector 1 and pipette 2, wherein the saliva collector portion 1 has an exterior surface with a salivation catalyst positioned directly thereon (Col.5: 3-5).

Conclusion

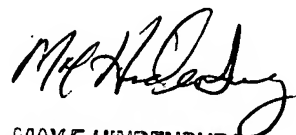
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN
8/3/2007



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